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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,325	02/20/2004	Steven W. Andrews	17465DIV(AP)	6873

7590

07/07/2005

Robert J. Baran - T2-7H
Allergan, Inc.
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EXAMINER

SHAMEEM, GOLAM M

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/783,325

Applicant(s)

ANDREWS ET AL.

Examiner

Golam M. M. Shameem, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 42-46 and 51-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 and 47-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/20/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

This application is a DIV of 10/256,879 which claims benefit for domestic priority under 35 U.S.C. § 119(e) [to a provisional application 60/325,815 09/27/2001], is acknowledged.

Status of Claims

Claims 1-54 are currently pending in the application.

Receipt is acknowledged of amendment / response filed on June 09, 2005 and that has been entered.

Claims 42-46 and 51-54 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 02/20/2004, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-41 and 47-50 drawn to a compound and composition and the elected species as set forth found in Example 40, is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)). Therefore, the requirement for restriction is still deemed proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-41 and 47-50 are rejected under 35 U.S.C. § 102(b) as being anticipated by Walter *et al* (2000). Applicant claims substituted indole compounds, compositions and their methods of uses thereof. Walter *et al* also disclose the synthesis of several indole derivatives having similar utilities and at least one of them anticipates the instantly claimed invention of compound of formula I, wherein R^1 is NO_2 (b is integer of 1), R^2 is hydrogen or phenyl and R_a is $(CR_7R_8)_c-R^6$ wherein c is 0 and R^6 is morpholinyl [STN International, CAPLUS database, RN number, 262366-61-0, a copy is provided with this Office action], which reads on the instantly claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-41 and 47-50 are rejected under 35 U.S.C. § 102(a) as being anticipated by Glennon *et al* (2000). Applicant claims substituted indole compounds, compositions and their methods of uses thereof. Glennon *et al* also disclose the synthesis of several indole derivatives and at least one of them anticipates the instantly claimed invention of compound of formula I, wherein R^1 is halogen (Br), b is 1, R^2 is hydrogen and R_a is $(CR_7R_8)_c-R^6$ wherein c is 0 and R^6 is

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morpholinyl [STN International, CAPLUS database, RN number, 297754-04-2, a copy is provided with this Office action], which reads on the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-41 and 47-50 are rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-9 and 17 of US 6,765,012 B2 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter. The compounds taught by US '012 are similar to instant application because a reference anticipating one set of claim will render the other obvious and it would have been obvious to one of ordinary skill in the art at the time of the invention was made since US '012 teaches the generic compounds and compositions which are similar to the instantly claimed compounds and compositions. The subject matter claimed in the instant application is fully disclosed and covered in US '012 patent. Therefore, the disclosure of US '012 that teaches many permutation and combination substitutions (including various Markush variable substitutions, such as R_a , R_b^1 , R^2 ,

and specific proviso etc), which would easily place Applicants invention in possession of the public at the time of Applicants invention was filed. Therefore, in the instant case, one skilled in the chemical art would be motivated to choose to replace variable substitutions in permutation and combinations in core indole structure to obtain the desired products in view of the known teaching of the art. The claimed compounds are so closely related structurally to the homologous and /or analogous compounds of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Moreover, any other differences are but obvious structural modifications, which would be apparent to one skilled in the chemical art that can use similar substitutions, would expect to have the same or essentially the same results. Therefore, in looking at the instant claimed compounds as a whole, the claimed compounds would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

Remarks

In claim 1, line 5, page 2, variable R is selected from the group consisting of "D" and it is not clear what the Applicant is intending to encompass with this expression. Explanation and / or correction are required.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 7:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number

for this Group is (703) 308-7921. The Official fax phone numbers for this Group are 571-273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

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A handwritten signature in black ink, appearing to read "G. M. Shameem". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

GOLAM M. M. SHAMEEM, PH.D
PRIMARY EXAMINER

Golam M M Shameem, Ph.D.
Primary Examiner
Art Unit 1626
Technology Center 1600

June 24, 2005